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Registration Decision

Carfentrazone-ethyl

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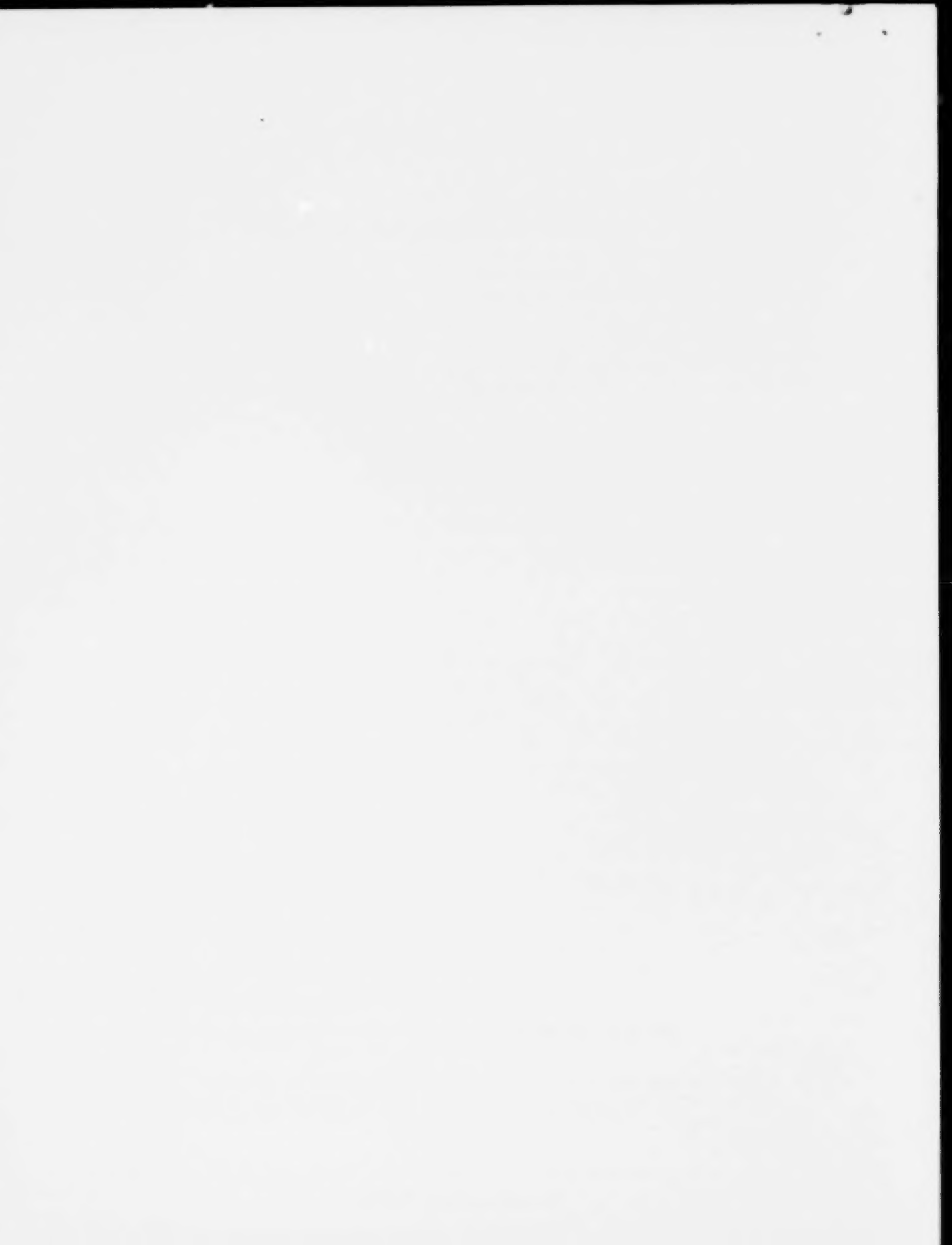
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Registration Decision for Carfentrazone-ethyl

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Aim (carfentrazone-ethyl) Technical Herbicide and Aim EC containing the technical grade active ingredient carfentrazone-ethyl to control weeds in numerous crops.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for full registration in the consultation document¹ Proposed Registration Decision PRD2009-06, *Carfentrazone-ethyl*. This Registration Decision² describes this stage of the PMRA's regulatory process for carfentrazone-ethyl and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2009-06. This decision is consistent with the proposed registration decision stated in PRD2009-06.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2009-06, *Carfentrazone-ethyl* that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable³ if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value⁴ when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

¹ "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

² "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

³ "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

⁴ "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What is Carfentrazone-ethyl?

Carfentrazone-ethyl is the active ingredient in Aim EC, a selective herbicide for use as a preplant burndown application in a fallow system or between the rows of a wide range of crops using a hooded sprayer application. Aim EC is also used as a harvest aid treatment to desiccate crops in order to facilitate harvest. One application of Aim EC applied as a broadcast treatment with ground application equipment will control several weed species.

Health Considerations

Can Approved Uses of Carfentrazone-ethyl Affect Human Health?

Carfentrazone-ethyl is unlikely to affect health when used according to label directions.

Exposure to carfentrazone-ethyl may occur through diet (food and water) or when handling and applying the product. When assessing health risks, two key factors are considered: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe the potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when using the carfentrazone-ethyl product according to label directions.

Aim EC caused eye and skin irritation in rabbits. Consequently, the statement "CAUTION—EYE AND SKIN IRRITANT" is required on the product label.

When tested in laboratory animals, carfentrazone-ethyl was not oncogenic, genotoxic or neurotoxic. Animal studies also demonstrated that carfentrazone-ethyl had no effects on reproductive toxicity, developmental toxicity, or teratogenicity. There was no evidence that carfentrazone-ethyl affected the immune and endocrine systems. The toxicity data did not demonstrate an increased sensitivity of the young to the toxic potential of carfentrazone-ethyl when compared to the adult animals.

Residues in Water and Food

Dietary risks from food and water are not of concern.

The refined chronic dietary exposure from all carfentrazone-ethyl food uses for the total population, including infants and children, and all representative population subgroups ranged from 11.8% to 47.7% of the acceptable daily intake. Aggregate exposure from food and water is considered acceptable and below the level of concern. The use of carfentrazone-ethyl on crops does not constitute an unacceptable chronic dietary risk (i.e. in food and drinking water) to any segment of the population, including infants, children, adults and seniors.

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Supervised residue trials conducted throughout the United States using end-use products containing carfentrazone-ethyl at the proposed rate and exaggerated rates in or on numerous crops are sufficient to support the proposed maximum residue limits.

Occupational Risks From Handling Aim EC

Occupational risks are not of concern when Aim EC is used according to the proposed label directions, which include protective measures.

Farmers and custom applicators who mix, load or apply Aim EC as well as field workers reentering recently treated fields can come in direct contact with carfentrazone-ethyl residues on the skin. Therefore, the label specifies that anyone mixing and loading Aim EC must wear a long-sleeved shirt, long pants, chemical-resistant gloves and shoes plus socks and that anyone applying the product must wear a long-sleeved shirt, long pants and shoes plus socks. Taking into consideration the label requirements, the expectation that occupational exposure is to be short-term for farmers and intermediate-term for custom applicators, and that the herbicide is applied only once per season, the risk to farmers, applicators or field workers is not a concern.

For bystanders, exposure is expected to be much less than that for workers and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When Carfentrazone-ethyl is Introduced Into the Environment?

Carfentrazone-ethyl poses a potential risk to terrestrial plants, therefore, risk-reduction measures must be observed.

When carfentrazone-ethyl is applied for control of weeds in crops, some of the active ingredient finds its way into soil and water. Carfentrazone-ethyl, however, is rapidly broken down by soil microbes and by chemical reaction in water. Thus, it is not expected to persist in the environment. Its major transformation products will be present in soil and aquatic systems for a longer period of time. Laboratory studies indicate that carfentrazone-ethyl and its transformation products are mobile in soil. However, there is no field evidence that the use of this herbicide will result in groundwater contamination, indicating that leaching in soil is offset by biotransformation processes. Therefore, potential for groundwater contamination would be low.

When carfentrazone-ethyl is used for weed control in crops, there is a potential that non-target plant species on land and in water may be exposed to the chemical as a result of spray drift or runoff. Some plant species are sensitive to carfentrazone-ethyl and would be adversely affected. To minimize the potential exposure, strips of land (buffer zones) between the agricultural field and the non-target terrestrial or aquatic areas will be left unsprayed. Carfentrazone-ethyl presents negligible risk to wild birds and mammals, bees and other arthropods as well as to aquatic organisms like fish, amphibians, invertebrates and plants. The width of these buffer zones will be specified on the product label.

Value Considerations

What is the Value of Aim EC?

Aim EC is used for the control of weeds in numerous crops.

For the control of several broad leaf weeds, Aim EC may be applied in a fallow system or as a preplant burndown in succulent or dried legume vegetables, fruiting vegetables, cucurbit vegetables, cereal grains, oilseeds and potatoes.

Aim EC may be applied using hooded sprayers between the crop rows in root and tuber vegetables, bulb vegetables, leafy vegetables, brassica (cole) leafy vegetables, succulent or dried legume, fruiting vegetables, cucurbit vegetables, pome fruits, stone fruits and berries to control several broad leaf weeds.

Aim EC may be applied as a harvest aid treatment to dried shelled peas and beans, potatoes, soybeans, barley, millet, oats, sorghum, triticale and wheat.

Carfentrazone-ethyl is compatible with integrated weed management practices and with conservation tillage and conventional crop production systems. Carfentrazone-ethyl is applied after weed emergence; therefore, growers can better assess whether the herbicide is suitable for the particular weed species present. Carfentrazone-ethyl also provides control of both conventional and glyphosate tolerant volunteer canola.

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the label of Aim EC to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

- As there is a concern with users coming into direct contact with Aim EC on the skin or through inhalation of spray mists, anyone mixing and loading Aim EC must wear a long-sleeved shirt, long pants, chemical-resistant gloves, shoes plus socks. Anyone applying the product must wear a long-sleeved shirt and long pants. In addition, standard label statements to protect against drift during application are on the label.

Environment

- Mitigative measures are required to protect sensitive terrestrial and aquatic plant species from the use of carfentrazone-ethyl. These mitigative measures include precautionary statements on the label regarding environmental hazards and the directions for use as well as a 3 meter buffer zone to protect sensitive plants from spray drift.

Other Information

The relevant test data on which the decision is based (as referenced in this document) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service.

Any person may file a notice of objection⁵ regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website (Request a Reconsideration of Decision, <http://www.hc-sc.gc.ca/cps-spc/pest/protect-proteger/publi-regist/index-eng.php#rrd>) or contact the PMRA's Pest Management Information Service.

⁵ As per subsection 35(1) of the *Pest Control Products Act*.

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